

REMARKS

Claims 1-8 and 11-36 are pending.

Objections

Claim 25 is objected to as dependent on a rejected claim. In view of arguments presented herein below, applicants assert that the objection of claim 25 is obviated thereby.

Rejection Under 35 U.S.C. § 102

Claims 1-8, 11-24, and 26-36 have been rejected under § 102(e) as allegedly anticipated by U.S. Patent No. 5,602,309 (issued to Albers et al.). This rejection is respectfully traversed for the reasons set forth herein below.

The Examiner contends that Albers et al. teach transgenic isolated hair sheath tissue (Title, col. 8, lines 22-24). For the purposes of clarity, Applicants have incorporated lines 22-27 of column 8 herein:

*“Dense hybridization was also found in **epidermal cells** of the outer root sheath of hair and vibrissa follicles of transgenic mice (FIG. 3d), but not in the corresponding areas of nontransgenic (FIG. 3c). The epidermal and hair follicle distribution of hybridization is consistent with the known expression pattern of the K14 keratin (Schweizer and Winter, 1982; Kopan and Fuchs, 1989).” (emphasis added)*

Applicants also respectfully refer the Examiner to the Albers et al. patent at column 7, lines 14-21, wherein it is stated:

*“NGF was overexpressed in the **epidermis** of transgenic mice using a fusion gene construct in which the human **epidermal K14 keratin promoter and enhancer** sequences were linked to a mouse NGF cDNA (FIG. 1a). The K14 promoter has previously been shown to direct high level of expression of various transgenes to basal keratinocytes of the epidermis.” (emphasis added)*

In contrast, the claims of the present invention are directed to a therapeutic composition, comprising isolated **dermal sheath tissue** and/or a cell derived therefrom comprising at least one selected gene, or functional fragment thereof, wherein the dermal sheath tissue is part of a gene therapy vehicle for targeted delivery. In that dermal sheath tissue is **mesenchymal** in origin and the transgenic isolated hair sheath tissue of Albers et al. is epithelial, which is **ectodermal** in origin, applicants assert that the tissue and/or cells described by the present invention differ from those of Albers et al. with respect to both structure and function.

It is well accepted that three functionally and structurally distinct germ cell layers (*i.e.*, the endoderm, mesoderm, and ectoderm) form during the course of embryonic development and give rise to functionally and structurally distinct tissues and cell types. Cells of the endoderm, for example, ultimately develop into a variety of tissue types, including the intestines. Cells of mesodermal origin differentiate into a variety of tissue types, including muscle. Cells of the ectodermal germ layer develop into, for example, central and peripheral nerves and the epidermis of skin. Although the three different germ cell layers ultimately become specialized, the differentiated cells that arise from each of these distinct layers retain certain characteristic features in their final developed form.

More specific information regarding distinctions among the embryonic germ cell layers is retrievable from electronic databases, which are readily accessible to the public. As defined by the American Heritage® Dictionary of the English Language: Fourth Edition (2000), for example, mesenchyme is the “part of the embryonic mesoderm, consisting of loosely packed, unspecialized cells set in a gelatinous ground substance, from which connective tissue, bone, cartilage, and the circulatory and lymphatic systems develop.” The American Heritage® Dictionary of the English Language: Fourth Edition (2000), defines ectoderm as the “outermost of the three primary germ layers of an embryo, from which the epidermis, nervous tissue, and, in vertebrates, sense organs develop.”

The mesenchymal origin of the dermal sheath tissue of the present invention is reflected in the differentiation potential of this tissue. As described throughout the

specification and specifically detailed in Figure 12, for example, and the description thereof at page 13, line 20 through to page 14, line 11, the dermal sheath tissue of the present invention has the potential to differentiate into cells of the muscle lineage (Figures 12B, C, G, H, and I), adipocyte cells, chondrocyte (cartilage-type) cells, and bone precursor cells. See also page 26, line 6 through to page 28, line 11, wherein these findings are described in detail. Inasmuch as the transgenic isolated hair sheath tissue of Albers et al. is epithelial, as indicated throughout Patent No. 5,602,309, and understood in the art because the K14 keratin promoter and enhancer sequences driving transgene expression are known to function in an epithelial cell specific manner, the isolated transgenic hair sheath tissue of Albers et al. is not capable of differentiating into muscle, adipocyte, chondrocyte, or bone cell lineage. In brief, epithelial cells are not known to be capable of differentiating into any of these mesoderm derived cell types. The profound differences in differentiation capacity of the cells of the present invention and those of Albers et al. underscore the many functional distinctions between the dermal sheath tissue as presently claimed and the isolated transgenic hair sheath epithelial cells described in Patent No. 5,602,309.

Moreover, from a morphological perspective, epidermal cells are structurally quite distinct from the dermal sheath cells of the present invention. These structural differences are also revealed in the differential staining patterns observed when these cell types are stained for the expression of cell markers characteristic of their divergent developmental lineages. It should, therefore, be apparent that the **dermal** sheath tissue of the present invention is structurally and functionally distinct from that of the transgenic **epithelial** hair sheath tissue of Albers et al.

In view of the above, applicants contend that the rejection of claims 1-8, 11-24, and 26-36 under 35 U.S.C. §102(e) is improper and respectfully request that the rejection be withdrawn.

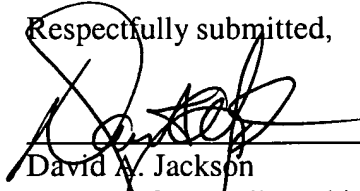
Fees

No additional fees are believed to be necessitated by this amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

Conclusion

It is submitted, therefore, that the claims are in condition for allowance. No new matter has been introduced. Allowance of all claims at an early date is solicited. In the event that there are any questions concerning this amendment, or application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,



David A. Jackson
Attorney for Applicant(s)
Registration No. 26,742

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack, New Jersey 07601
(201) 487-5800

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Enclosures: Petition for a Five-Month Extension of Time
Request for Continued Examination (RCE)